

TEVADAPTOR® Closed Drug Reconstitution and Transfer System

Cyto IV Set with 0.2 Micron filter



Enhanced
"2 way spike"
IV line with
inline 0.2
micron filter

TECHNICAL DATASHEET

Cyto IV Set with 0.2 Micron filter:

The Tevadaptor® Cyto IV set enhances the Infusion Set 180 by addition of an inline 0.2 micron filter, for use with drugs that need to be micro filtered upon administration. The Cyto IV set firmly connects between a standard IV bag or polyethylene bottle to any patient IV catheter via a luer lock connection. A safe drug transfer from the syringe into the IV bag or container is enabled through the closed connection with the Tevadaptor® Syringe Adaptor/ Syringe Adaptor Lock. During manipulation the "click" sound indicates a safe and secure connection between the two components. The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces. The smart "2-way spike" helps protect against accidental entrance of concentrated drug into the patient's IV line. The separate "fluid-in path" ensures that the injected concentrated drug solution will flow into the bag or container for dilution and not into the tubing, in case the pinch clamp is left open after priming. After appropriate dilution, the drug is safely administered to the patient through the "fluid-out path" and the Cyto IV Set.

Intended use:

Tevadaptor® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of the drug in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

TDPT-IL-00078

TECHNICAL DATASHEET CYTO IV SET WITH 0.2 MICRON FILTER

Order Information

Article number / Reference	1MG245535
User box quantity	50 pcs
Transport box quantity	50 pcs

Product Characteristics

Product Technical data	
Tubing length	180 cm
Volume of the tubing	20 ml
Spike type	Non-vented, 2-way spike with a "fluid-in path" and a "fluid-out path"
Filter size	0.2 micron
Distal end of the tubing	Male luer lock connection with flow-stop protection cap
Clamp type	Pinch clamp and roller clamp
Septum piercings	Up to ten times
Shelf life	3 years
Sterilization	Ethylene Oxide
Drip chamber and drip tube	1ml=20 drops of distilled water

Tolerates disinfection with alcohol 70% and chlorhexidine in alcohol (5 mg/70% alcohol)

Material Specifications

Component	Material
Protective cap on spike	Polyethylene
2-way Spike	ABS
Elastomeric sealing	Polyisoprene
Soft tubing	DEHP-free PVC
Pinch clamp on tubing	Acetal
Male luer lock body and collar on distal end of tubing	ABS
FlowStop protection cap	Acrylic copolymer membrane (hydrophobic)
Drip chamber	DEHP-free PVC and ABS
Roller clamp	ABS
0.2 Micron filter	MBS-Cyrolite, PES-Polyethersulfone and PTFE

DEHP-free PVC. Non-pyrogenic. Free from latex, lead, cadmium, arsenic and chrome. Meets standards and regulations with regards to the environment

Regulation

CE 0483
FDA 510(k) Cleared under ONB product code



Consult instruction for use



Non-pyrogenic



Do not re-sterilize



Single use only, do not re-use



Not made with DEHP



Not made with natural rubber latex



Do not use if package is damaged



Keep dry



Keep away from sunlight



CE 0483



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Disposal of components should be according to local regulations and procedures for handling of hazardous drugs.

References:

1. https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141448.pdf

TEVADAPTOR[®]

Keeps you safe in a click